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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ELAN PHARMA INTERNATIONAL LTD. and FOURNIER LABORATORIES IRELAND LTD.,	)	
Plaintiffs,	)	**Civil Action No. _____**
v.	)	
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Elan Pharma International Ltd. ("Elan") and Fournier Laboratories Ireland Ltd. ("Fournier") for their Complaint against Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") (collectively "Lupin") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 7,276,249 ("the '249 patent") and 7,320,802 ("the '802 patent"). This action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of the highly successful TRICOR® 48 mg and 145 mg products prior to the expiration of Plaintiffs' patents.

THE PARTIES

2. Plaintiff Elan Pharma International Ltd. is an Irish corporation having a principal place of business at Monksland, Athlone, Co. Westmeath, Ireland.

3. Plaintiff Fournier Laboratories Ireland Ltd. is an Irish corporation having a principal place of business at Anngrove, Carrigtwohill, Co. Cork, Ireland.

4. On information and belief, Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (W), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. On information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products through various operating subsidiaries, including Lupin Pharmaceuticals.

5. On information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland, 21202. On information and belief, Lupin Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Lupin Pharmaceuticals in a wholly-owned subsidiary of Lupin Ltd.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. On information and belief, this Court has personal jurisdiction over Lupin Ltd. because Lupin Ltd. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Ltd. has had persistent and continuous contacts with this judicial district, including developing and/or manufacturing pharmaceutical products that are sold in this judicial district.

8. On information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals because Lupin Pharmaceuticals has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, manufacturing, and/or selling pharmaceutical products that are sold in this judicial district.

9. On information and belief, Lupin Pharmaceuticals participated in, contributed to, aided, abetted, and/or induced the submission to the United States Food and Drug Administration ("FDA") of the ANDA at issue in this case.

10. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals operate as an integrated, unitary business. For example, Lupin Ltd. includes within its Annual Report the activities of Lupin Pharmaceuticals, including revenue earned.

11. On information and belief, Lupin Pharmaceuticals is registered to do business in New Jersey.

12. On information and belief, Lupin Pharmaceuticals has appointed National Registered Agents, Inc. of Princeton, New Jersey, as its registered agent for the receipt of service of process.

13. Lupin Ltd. and Lupin Pharmaceuticals stipulated in a previous litigation to personal jurisdiction in this Court. *See* Dec. 17, 2006 Stipulation and Order, *Sepracor Inc. v. Sun Pharmaceutical Industries Ltd.*, Case No. 07-4213 (D.N.J.).

14. Two related lawsuits are currently pending in this Court. On February 29, 2008, Elan and Fournier filed suit in this Court against Teva Pharmaceuticals USA, Inc. ("Teva") seeking a judgment that each of the '249 and '802 patents, in addition to one other patent, is infringed by Teva's filing of its ANDA No. 90-069. *See Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Teva Pharmaceuticals USA, Inc.*, Case No. 08-1085 (D.N.J.). On November 3, Elan and Fournier filed suit in this Court against Biovail Laboratories International SRL and Biovail Corporation (collectively "Biovail") seeking a judgment that each of the '249 and '802 patents, in addition to one other patent, is infringed by Biovail's filing of its ANDA No. 90-715. *See Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Biovail Laboratories International SRL and Biovail Corp.*, Case No. 08-5412 (D.N.J.).

15. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

BACKGROUND

16. On October 2, 2007, the '249 patent, entitled "Nanoparticulate Fibrate Formulations," was duly and legally issued to Elan and Fournier as assignees. A true and correct copy of the '249 patent is attached as Exhibit A.

17. On January 22, 2008, the '802 patent, entitled "Methods of Treatment

Using Nanoparticulate Fenofibrate Compositions," was duly and legally issued to Elan and Fournier as assignees. A true and correct copy of the '802 patent is attached as Exhibit B.

18. On November 5, 2004, the FDA approved New Drug Application ("NDA") No. 21-656 for TRICOR® tablets, which contain fenofibrate, under § 505(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a), as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia and to reduce elevaled LDL-C, Total-C, Triglycerides and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia, or mixed dyslipidemia.

19. The '249 and '802 patents are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for TRICOR® tablets.

20. On information and belief, Lupin Ltd., itself and/or through its subsidiary, agent and alter ego, Lupin Pharmaceuticals, submitted ANDA No. 90-856 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of fenofibrate tablets in 48 mg and 145 mg dosages ("Lupin's Tablets, 48 mg and 145 mg"), as generic versions of the TRICOR® 48 mg and 145 mg tablets. Upon information and belief, Lupin Pharmaceuticals will market and/or distribute Lupin's Tablets, 48 mg and 145 mg, if ANDA No. 90-856 is approved by the FDA.

21. By letter dated January 22, 2009, Lupin Ltd. advised Elan and Fournier that it had submitted ANDA No. 90-856 seeking approval to manufacture, use, or sell Lupin's Tablets, 48 mg and 145 mg, prior to the expiration of the '249 and '802 patents.

22. The January 22, 2009 letter also advised Elan and Fournier that Lupin's ANDA included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Lupin's opinion, the '249 and '802 patents are invalid and/or will not be infringed by the commercial manufacture,

use, or sale of Lupin's Tablets, 48 mg and 145 mg.

COUNT I

23. Plaintiffs incorporate each of the preceding paragraphs 1-22 as if fully set forth herein.

24. By filing ANDA No. 90-856 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Lupin's Tablets, 48 mg and 145 mg, prior to the expiration of the '249 patent, Defendants have committed an act of infringement, and/or induced infringement, of the '249 patent under 35 U.S.C. § 271(e)(2).

25. The commercial manufacture, use, offer to sell, sale, or importation of Lupin's Tablets, 48 mg and 145 mg, would infringe one or more of the claims of the '249 patent under 35 U.S.C. § 271.

26. On information and belief, Lupin was aware of the existence of the '249 patent and was aware that the filing of its ANDA and certification with respect to the '249 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

27. Plaintiffs incorporate each of the preceding paragraphs 1-22 as if fully set forth herein.

28. By filing ANDA No. 90-856 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Lupin's Tablets, 48 mg and 145 mg, prior to the expiration of the '802 patent, Defendants have committed an act of infringement, and/or induced infringement, of the '802 patent under 35 U.S.C. § 271(e)(2).

29. The commercial manufacture, use, offer to sell, sale, or importation of Lupin's Tablets, 48 mg and 145 mg, would infringe one or more of the claims of the '802 patent

under 35 U.S.C. § 271.

30. On information and belief, Lupin was aware of the existence of the '802 patent and was aware that the filing of its ANDA and certification with respect to the '802 patent constituted infringement of that patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Lupin has infringed the '249 and '802 patents;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Lupin's ANDA No. 90-856 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), be a date which is not earlier than the expiration date of the '249 and '802 patents;

C. An injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Lupin and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from infringement of the '249 and '802 patents for the full terms thereof;

D. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

E. Costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper.

CERTIFICATION PURSUANT TO L. CIV.R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L.CIV.R. 11.2 that the matters in controversy are not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding, with the exception of the related lawsuits identified in Paragraph 14 of this Complaint involving different defendants but the same Patents-in-Suit.

Respectfully submitted,

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